MARK W. MATTIOLI
Assistant Attorney General
Agency Legal Services Bureau
1712 Ninth Avenue
P.O. Box 201440
Helena, MT 59620-1440
Telephone: (406) 444-2026
Facsimile: (406) 444-4303
mmattioli@mt.gov

COUNSEL FOR DEFENDANTS

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
HELENA DIVISION

THOMAS SCOTT ANDERSON, Plaintiff, vs. MONTANA DEPARTMENT OF CORRECTIONS, MIKE BATISTA, Director of the Montana Department of Corrections, LEROY KIRKEGARD, Warden of the Montana State Prison, and DR. KOHUT, individually and in their official capacities, Defendants.	Case No. CV 15-00031-H-DLC-JTJ **DECLARATION OF TRISTAN E. KOHUT, DO**

I, Tristan E. Kohut, declare under penalty of perjury that the following is true and correct:

1. I am over the age of 18, am competent to testify to the facts contained herein, and have personal knowledge of the facts and statements contained in this Declaration.

2. At all material times herein, I have been employed with the Montana Department of Corrections (DOC), at the Montana State Prison, as a staff physician and as acting medical director of the DOC.

3. I am a Doctor of Osteopathic Medicine (DO), having obtained my DO degree in 1982 from the Philadelphia College of Osteopathic Medicine in 1982, after which I did a three-year residency in family medicine at the Garden City Hospital in Garden City, Michigan. I am currently studying for a master's degree in health care administration. My undergraduate degrees are in Natural Sciences and Chemistry.

4. I have been board certified in General Practice/Family Practice by the American Board of Osteopathic Family Practice since 1985, having practiced in the states of Pennsylvania, Michigan, Oklahoma, South Dakota, Texas, Ohio and Maine. I have been licensed to practice in Montana since 2006 (No. 11151), and a member of the American Osteopathic Association, American College of Osteopathic Family Practice, Montana Osteopathic Medical Association, Association of Military Osteopathic Physicians and Surgeons, National

Commission on Correctional Health Care, American College of Healthcare Executives and the American Society of Correctional Physicians.

5. Prior to beginning work for the Montana DOC, I served with the Medical Corps of the United States Air Force, retiring in 2005 as a Lieutenant Colonel after 20 years of service as Chief Family Practice physician. At various times I have served as chief and deputy chief of hospital services and as department head at 200 and 250-bed hospitals. I provided a full spectrum of family practice care for active duty personnel and their families, as well as retired Armed Forces families. I managed physicians and medical support personnel and clinic operations, credentialed new physicians and mid-level healthcare providers, developed peer review programs, taught combat casualty care, and served on a medical mission to provide humanitarian care to the Honduran civil population.

6. I began my work as staff physician at the Montana State Prison in 2006 and since 2012 have been serving as the acting medical director, Montana Department of Corrections. As a staff physician, I provide a full spectrum of family practice services to incarcerated individuals, including acute medical care management, chronic medical disease/condition management, and limited infirmary medical care management. This includes, but is not limited to, ordering diagnostic studies, prescribing medical treatment and performing minor surgical procedures. I recommend specialty care consultations, consult and work with

outside specialists, and oversee midlevel care, including direct supervision and chart review. As acting medical director I review outside specialty consultations, review non-formulary pharmaceutical requests, coordinate care involving Montana inmates, and establish standard procedures, protocols, and policies for the DOC.

7. I have reviewed the DOC's medical records with respect to the Plaintiff, Thomas Scott Anderson, DOC ID# 3013458.

8. Mr. Anderson came to MSP in October 2014 with a recently diagnosed Hepatitis C infection, which he reported having contracted through his recent intravenous drug use. The infection was diagnosed by medical providers at Benefis Hospital in Great Falls during Anderson's incarceration at the Cascade County Detention Center.

9. Within one month of Anderson arriving at MSP the Benefis medical records were reviewed. Those records include liver panels showing elevated liver enzymes consistent with hepatitis or inflammation of the liver. On April 20, 2013, the AST level was 516; and the ALT enzyme—which is considered a much more important marker of Hepatitis C-caused liver inflammation—was 1654. Less than four months later, on August 7, 2013, the AST had decreased to 211 and the ALT had decreased to 531. This significant decrease in AST and ALT levels is likely due to the circumstances of Mr. Anderson's incarceration, most importantly forced abstinence from alcohol and intravenous drug use.

10. The Benefis records reveal that Anderson was examined by PA Scott in September 2013. Anderson denied abdominal pain, gastrointestinal bleeding, or mental confusion. PA Scott noted that total bilirubin and alkaline phosphatase levels were normal. Anderson denied fatigue, fever, weight gain or loss, and night sweats. He was not jaundiced, displayed no abdominal tenderness or hepatic enlargement, and he did not have stigmata of chronic liver disease.

11. Anderson's liver was biopsied at Benefis by Dr. Ayers in September 2013. The pathology report states a diagnosis of hepatitis with periportal chronic inflammation and focal or rare piecemeal necrosis and lobular inflammation. Notably, however, the report states that there was "no fibrosis."

12. Anderson arrived at MSP in October 2014. At that time, Anderson reported low back pain. His primary medical complaints during his time at MSP have been unrelated to hepatitis, including sciatic, neck and low back pain and depression, anxiety and rage. Anderson is a 32-year-old man. He has an asymptomatic chronic Hepatitis C infection. He is otherwise in generally good medical condition and health. Mr. Anderson's medical complaints have been handled appropriately during his time at MSP.

13. Within two months of Anderson arriving at MSP, additional liver function tests were ordered. On December 17, 2014, the AST had decreased to 159 and the ALT had decreased to 350.

14. I saw Mr. Anderson on January 6, 2015. At that time I noted that Anderson had a recent Hepatitis C diagnosis and that a September 2013 biopsy showed no fibrosis. I discussed this with Anderson and informed him that if liver function tests increased I would consider ordering further testing to determine progression.

15. In May 2015, PA Griffin ordered another liver panel, which showed the AST decreasing to 84 and the ALT decreasing to 190. Another liver panel was done in November 2015 and the results were similar: AST of 74 and ALT of 210. These decreases in liver enzymes, in particular the ALT levels, are in my opinion attributable to the fact that Anderson's has not been abusing substances toxic to the liver, in particular intravenous drug use.

16. There are over a million people infected with the Hepatitis C virus in the United States. It is an infection of the baby boomer generation. The primary mode of transmission is intravenous drug use. The disease can be transmitted by sexual contact. Mr. Anderson has a history of both tattooing and IV drug abuse.

17. The incidence of infection in prison environments is significantly higher than in the general population. All Montana DOC prisoners are required to be tested for Hepatitis C, and I estimate that approximately 30% of Montana's over 2,000 inmates have been infected. There are false positive tests and the virus will clear spontaneously in some individuals. However, even if the percentage of

chronically-infected inmates is as low as 20%, the number of infected DOC inmates would still be in the hundreds.

18. Managing Hepatitis-C infected patients in the prison context necessitates guidelines for the management and treatment of this patient population. Patients who test positive for the Hepatitis C antibody are enrolled in the Hep C database, offered Hep A/B prophylaxis, and ALT levels are measured at six-month intervals. If the ALT level exceeds more than two times the normal upper limit (11-79 U/L) on two consecutive blood draws, a viral load and genotype is ordered. Mr. Anderson's ALT levels met this standard. Thus, his genotype was obtained. Anderson's genotype is 1a. It is quite common, both in correctional and in the community healthcare contexts, for a person in Mr. Anderson's ALT range, i.e., an ALT between two and three times the normal upper limit, to be monitored rather than given drug therapies. Anderson's viral load was 2,090,000 in December 2014 and 1,555,000 in June 2015. The viral load is obtained to ascertain whether a patient is considered chronically infected because a significant percentage of persons infected with the virus will clear the virus spontaneously. The viral load is not considered a reliable prognostic indicator or a measure of the extent of virus-caused liver disease. Viral load is used to determine whether drug treatment has eradicated the virus. Again, although viral load is not a reliable

prognostic tool or measure of liver damage, Anderson's viral load was in the low-medium range. The average viral load is about 6,000,000.

19. I have significant experience managing and treating patients infected with the Hepatitis C virus. I also consult with specialists in the field. While guidelines for management of the patient population are necessary and helpful due to high rates of infection and to prioritize those whose needs are the greatest, in all cases the primary consideration is the patient's overall health and the health care provider's clinical assessment and judgment.

20. Because Anderson's ALT levels have been more than twice the normal upper limit (11-79 U/L) in consecutive blood draws, Anderson's ALT level and overall condition have been and will continue to be monitored every six months. Estimates vary, but possibly 15-30% of individuals chronically infected with Hepatitis C will go on to develop cirrhosis, and there is also a small risk of cancer in patients with cirrhosis. Mr. Anderson does not have cirrhosis. Although the vast majority of chronically-infected patients do not develop cirrhosis, if it does occur, it may take 10-20 years or more for cirrhosis to develop. In my opinion in Mr. Anderson's particular case drug treatment is not required at this time. Medical monitoring of his condition does not expose him to an unreasonable or significant risk of harm, and in my opinion he is not at significant risk of harm while he is being monitored. This medical judgment is based upon a number of factors or

considerations, including, without limitation, Anderson's general health status and clinical presentation, his ALT levels, the September 2013 biopsy report which revealed "no fibrosis," and the fact that Mr. Anderson's ALT levels have declined significantly during his relatively short time in prison. If Mr. Anderson's overall health deteriorates, I would order additional tests to determine progression and treat accordingly.

21. Recently, beginning in late 2013, the U.S. Food and Drug Administration has approved promising new drugs to treat Hepatitis C, including genotype 1 infection, which until very recently had been very difficult to treat. These drugs include Olysio (approved November 2013), Solvaldi (approved December 2013), Harvoni (approved October 2014), and Viekira Pak (approved December 2014). These treatments are effective in clearing the virus, including in patients who have developed fibrosis and cirrhosis. The treatments can actually reverse fibrosis, provided the patient maintains a sober lifestyle. In Mr. Anderson's case, in my medical judgment treatment with these drugs is not indicated or medically necessary at this time. However, as a practical matter, even if Mr. Anderson were in the community he would confront substantial obstacles to obtaining these new treatments, as both Medicaid and private insurers have imposed eligibility criteria for these new treatments. As discussed above, Mr. Anderson's ALT levels have declined, his overall clinical health and presentation

is good, and a recent biopsy revealed no fibrosis of his liver. These medications are generally not covered by public or private insurers under these circumstances. In addition, community health care providers would be required to address concerns about the risk of reinfection and amenability to treatment. Anderson appears to have been infected through intravenous drug use as well as use of contaminated equipment. He has not undergone or successfully completed chemical dependency treatment.

22. After reviewing Mr. Anderson's file, I believe he has received adequate and indeed good care while at MSP. I am not unconcerned about or ignoring his Hepatitis C infection. Mr. Anderson is being monitored medically and he will continue to be monitored regularly and adequately according to his medical needs.

23. Treatment providers, including in the correctional context, are currently in the process of adjusting to the introduction of new medicines to treat Hepatitis C infection. The DOC is presently working on developing guidelines in accordance with current community, Medicare and Medicaid standards. Treatment for patients infected with Hepatitis C is challenging. The treatment regime is unpredictable. Treatment modalities are in a constant state of flux, with treatment protocols coming into effect and then being modified within a matter of weeks or

months. Additional treatment regimens are due for FDA approval, shortly, and may offer greater availability to the infected population.

I declare under penalty of perjury that the foregoing is true and correct.

DATED this 28th day of January, 2016.

By: _____
TRISTAN E. KOHUT, DO